UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,881	03/15/2002	Howard Kaufman	MDS-030	5399

51414 7590 03/14/2005

GOODWIN PROCTER LLP
PATENT ADMINISTRATOR
53 STATE PLACE
EXCHANGE PLACE
BOSTON, MA 02109-2881

EXAMINER	
MISTRY, O NEAL RAJAN	

ART UNIT	PAPER NUMBER
2625	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,881	KAUFMAN ET AL.	
	Examiner	Art Unit	
	O'Neal R Mistry	2625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-39* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application has been examined.

Claims 1-39 are presented for examination.

Drawings

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13, 14, 15, 16, 18, 25, 31, 33, 34, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998).

In regards to claim 1 & 18, Thirion states a method of relating a plurality of images of a tissue, said method comprising: obtaining a plurality of images of a tissue (Figure 6, Note that the image 1 & image 2); determining a relationship between two or more regions in each of two or more of said images (Figure 2 & Figure 1a & Figure 1b, Note that the system is comparing to two areas of the images to calculate the difference to view any changes from the image 2 to image 1, and to see if they are similar. If there two images that are similar, which means the lesion within the skin in not growing.); segmenting at least a subset of said two or more images based at least in part on said relationship (Figure 6 item 70, col. 10 lines 14-15, Note that the system is segmenting the image to capture the lesion portion of the image.); and relating two or more images

of said subset of images based at least in part on said segmenting (col. 12 lines 48-51, Note the examiner interprets that the two images, the relating images have a common subset is the lesion located on Figures 1a & 1b. In addition, the lesion are segmented into smaller images as demonstrated by Figures 3 & Figures 4).

In regards to claim 2, Thirion states determining a measure of similarity between at least two of said two or more regions in each of said two or more of said images (col. 7 lines 37-42, Note that the system is making a comparision between both lesion of image 1 and image 2, figure the similarlities. In addition, Figures 4a, 4b & Figures 5a, 5b, show the same lesion, and the comparison of between the first and second.) [F.sub.1 and F.sub.2 are t he respective shapes of the active lesions in the first and second images. F.sub.1 and F.sub.2 belong to the same space E as D.sub.2,1. There is therefore the following relationship: F.sub.1 =D.sub.2,1 (F.sub.2), which means that the shape F.sub.1 of the active lesion of the first image is equal to the transform by the deformation vector field D.sub.2,1 of the shape F.sub.2 of the same active lesion of the second image (reference image).].

In regards to claim 13, Thirion discloses obtaining of said plurality of images comprises recording visual images of said tissue (Figure 6 item 10, Note the examiner interprets the word "recording" in the claims has a register electronically as stated in the dictionary of www.ONELOOK.com. In addition, in Figure 6 item 10, is used to register the images within the system).

In regards to claim 14, Thirion states relating step comprises determining a segmentation mask of an image plane wherein two or more regions of said image plane are differentiated (col. 12 lines 15-20) [More precisely (see FIG. 7), the selection/determination of the areas of interest comprise, first of all the production of a mask 51 from the second image (reference image), and the combination of this mask, by a logic operation of the "ET" type 52 with one of the sets of difference data resulting from the application to the deformation vector field D of at Least one of the operators.].

In regards to claim 15, Thirion discloses defining one or more data series representing a characteristic (Figure 6 item 10, Note item 10 is used to register the image data and characteristics of the image) of one or more associated segmented regions of an image plane (Figure 6 item 70.).

In regards to claim 16, Thirion discloses a method of relating a plurality of images of a tissue, said method comprising: obtaining a plurality of images of a tissue (Figure 6, Note that the image 1 & image 2); determining a measure of similarity between two or more regions in each of two or more of said images (Figure 2 & Figure 1a & Figure 1b, Note that the system is comparing to two areas of the images to calculate the difference to view any changes from the image 2 to image 1, and to see if they are similar. If the two images are similar than means the lesion is within the skin in not growing.); and relating at least a subset of said two or more images based at least in part on said measure of similarity (col. 12 lines 48-51, Note the examiner interprets that the two

images, the relating images have a common subset is the lesion located on Figures 1a & 1b. In addition, the lesion are segmented into smaller images as demonstrated by Figures 3 & Figures 4).

In regards to claim 25, Thirion discloses segmenting comprises analyzing an aceto-whitening signal. (Figure 2, Note that the examiner interprets that the lesion within the brain is white, or the white dot, and that could be applied to for analyzing aceto-whitening signals. In conclusion, the examiner interprets that aceto-whitening is used for view lesion tissue, and the brain tumor is the a lesion tissue within the brain.)

In regards to claim 28, Thirion discloses the segmenting comprises determining a gradient image (Figure 2A-2D, Note the examiner interprets that image changes the color.)

In regards to claim 31, Thirion discloses determining one or more regions of said tissue with a suspicion of pathology (col. 1 lines 11-17) [The invention applies more particularly, but not exclusively, to images termed medical images, and especially to the analysis of comparable digital images of regions of the brain, in order to study areas of interest comprising, for example, lesions or tumours, or active anatomical structures such as the heart or the ventricles of the brain.]

In regards to claim 33, Thirion discloses (a) for each of a first plurality of reference sequences of images of tissue (Figure 6, Note the image1 and image2) having a first known characteristic (Figures 1a &1b items L T, Note that L is for lesion,

and T is for tissue, and theses are characteristic of the image), quantifying one or more features of each of a plurality of mean signal intensity data series corresponding to segmented regions (Figure 6 item 70, Note that images are segmented, col. 10 lines 10-17) [In the diagram illustrated in FIG. 6, when a detection module 50 is not use id, the quantification module 60 is fed by the module for calculating the deformation field 35 and by the segmentation module 70 which provides the areas of interest in which Quantification is to be carried out. The segmentation module 70 may be integrated in the processing module 30.] represented in said each of said first plurality of reference sequences of images (col. 2 lines 50-55, Note that the system is providing different sets of data for each of the images);

(b) for a test sequence of images (Figures 2a & 2b, Figures 3a & 3b, Figures 4a & 4b, Note the examiner interprets that images demonstrate a test performed on the patient and images are sequence of results.), quantifying one or more features of each of one or more mean signal intensity data series corresponding to one or more segmented regions(Figure 6 item 70, Note that images are segmented, col. 10 lines 10-17) [In the diagram illustrated in FIG. 6, when a detection module 50 is not use id, the quantification module 60 is fed by the module for calculating the deformation field 35 and by the segmentation module 70 which provides the areas of interest in which Quantification is to be carried out. The segmentation

module 70 may be integrated in the processing module 30.]

represented in said test sequence of images (Figure 1a & Figure 1b item L & T, Note the examiner interprets that the L, lesion, is represented within the images, and T is demonstrated on the images as well, within the regions that are segmented.); and

(c) determining a characteristic of a tissue represented in said test sequence of images (Figure 1a & 1b items L & T, Note that the characteristic of tissue represented are the L, lesion, or T, tissue.) based at least in part on a comparison between said one or more features quantified (Figure 6 item 80) in step (a) and said one or more features quantified (Figure 6 item 10) in step (b).

In regards to claim 34, Thirion discloses step (a) for each of a second plurality of reference sequences of images of tissue having a second known characteristic (Figures 1a & 1b, Note the examiner interprets that second characteristic is T, tissue, or L, lesion. These are the two types of characteristic tissue).

In regards to claim 38, Thirion discloses determining said segmented regions of said test sequence of images by analyzing an acetowhitening signal (Figure 2, Note that the examiner interprets that the lesion within the brain is white, or the white dot, and that could be applied to for analyzing aceto-whitening signals. In conclusion, the examiner interprets that aceto-whitening is used for view lesion tissue, and the brain tumor is the a lesion tissue within the brain.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Butler et al (U.S. Patent Number 5,267,179).

In regards to claim 3, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "said determining of said measure of similarity comprises computing an N-dimensional dot product of mean signal intensities of two of said two or more regions ".

Butler teaches a system which stores images and compares the images for resemblance similar to that of Thirion. In addition, Butler further teaches wherein said determining of said measure of similarity comprises computing an N-dimensional dot product of mean signal intensities of two of said two or more regions (col. 2 lines 48-52) [In addition, a means is provided to measure the short circuit photocurrent across the first and second electrodes which is the two-dimensional dot product of the stored and projected images and an indication of the degree of similarity between these images.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Butler before him at the time the invention was made, to modify the method of searching similarity between two images taught by Thirion to include the the dot product method for find similarity of Butler, in order to obtain a system that searches two different tissue samples to find similarities between them by the method of using dot product.

One would have been motivated to make such a combination because the device will be able to perform the necessary correlations at great speed without the need fro many components (col. 1 line 67-col. 2 line 2) would have been obtained, as taught by Butler.

Claims 4 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Blair (U.S. Patent Number 6,277,067)

In regards to claim 4 & 24, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "said tissue comprises cervical tissue ".

Blair teaches a hand-held device that digitally display lesion similar to that of Thirion. In addition, Blair further teaches said tissue comprises cervical tissue (col. 5 lines 20-25) [The apparatus and associated method may be employed to create instantaneous digital images of cervical tissue for immediate viewing and digital image processing. More particularly, digital images created by the apparatus and method may be instantaneously processed to remove reflective glare or to perform any number of digital image enhancement operations for determination of tissue texture, tissue and lesion borders,].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Blair before him at the time the invention was made, to modify the tissue samples taught by Thirion to include the cervical tissue of Blair, in order to obtain a system that has the ability to compare the growth of lesion within the cervical tissue as well as other body part tissues.

One would have been motivated to make such a combination because it would allow a better diagnosis for different parts of the body, as taught by Blair. In addition, another motivation to combine the reference is that the processing of two medical images obtain at different moments has been described, and the process may equally apply to images in another field, as taught by Thirion.

Claims 5 &27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Utzinger (U.S. Patent Number 6,766,184)

In regards to claim 5, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "said plurality of images comprises sequential images of said tissue ".

Utzinger teaches a system for generating images of tissue samples similar to that of Thirion. In addition, Utzinger further teaches said plurality of images comprises sequential images of said tissue (col. 6 lines 43-46).

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Utzinger before him at the time the invention was made, to modify the images taught by Thirion to include the sequential set of image of Utzinger, in order to obtain a system that analyzes a sequential group of images for and compare the group of images to another set of sequential group of images.

One would have been motivated to make such a combination because there is a need for replacing traditional colposcopy to allow for accturate, real-time diagnosis. Specifically, a need exists for a technique that uses multispectral imaging techniques to provide high-resolution (col. 2 lines 47-55), as taught by Utzinger.

In regards to claim 27, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "segmenting comprises analyzing a variance signal."

Utzinger teaches a system for generating images of lesion tissuea similar to that of Thirion. In addition, Utzinger further teaches segmenting comprises analyzing a variance signal (col. 10 lines 50-62)

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Utzinger before him at the time the invention was made, to modify the analyzing signals taught by Thirion to include the variance calculation of Utzinger, in order to obtain a system that allows variance signals to be analyzed to generate images of lesion.

One would have been motivated to make such a combination because there is a need for replacing traditional colposcopy to allow for accturate, real-time diagnosis. Specifically, a need exists for a technique that uses multispectral imaging techniques to provide high-resolution (col. 2 lines 47-55), as taught by Utzinger.

Claims 6,7,21,22,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Burl (U.S. Patent Number 6,011,596)

In regards to claim 6 & 21, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite, "filtering said subset of said two or more images ".

Burl teaches a system takes video images and uses a method to display the images similar to that of Thirion. In addition, Burl further teaches filtering said subset of said two or more images (col. 2 lines 53-57, Note that the filtering is done to P1 and P2, which is the surface vectors of the images.) [After correlation surfaces P1 and P2 have been derived for corresponding blocks in f0 and f1, and f2 they are temporally filtered by being added together in a summer 2. This produces a correlation surface PT which can be used to assign vectors to input field f.sub.1.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Burl before him at the time the invention was made, to modify the filtering images taught by Thirion to include a system to have spatial and temporal filters for images of Burl, in order to obtain a system to filter the images to allow a better resolution of image processing.

One would have been motivated to make such a combination because it allows a better image to be displayed by processing the images through the spatial or temporal filter to allow better diagnosis, as taught by Burl.

In regards to claim 7 & 22, Thirion in view of Burl discloses wherein said filtering comprises applying at least one of a temporal filter (col. 8 lines 42-47) and a spatial filter (col. 4 lines 10-15).

In regards to claim 30, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite, "filtering at least one image based at least in part on said segmenting".

Burl teaches a system takes video images and uses a method to display the images similar to that of Thirion. In addition, Burl further teaches filtering at least one image based at least in part on said segmenting (col. 2 lines 53-57, Note that the filtering is done to P1 and P2, which is the surface vectors of the images.) [After correlation surfaces P1 and P2 have been derived for corresponding blocks in f0 and f1, and f2 they are temporally filtered by being added together in a summer 2. This produces a correlation surface PT which can be used to assign vectors to input field f1.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Burl before him at the time the invention was made, to modify

the filtering images taught by Thirion to include a system to have spatial and temporal filters for images that are segmented of Burl, in order to obtain a system to filter the images to allow a better resolution of image processing during segmenting the images into pieces.

One would have been motivated to make such a combination because it allows a better image to be displayed by processing the images through the spatial or temporal filter to allow better diagnosis, as taught by Burl.

Claims 8, 10, 11, 12, 19, 23, 29, 32, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Balas (US PUB 2002/0007123)

In regards to claim 8 &19, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "applying a chemical agent to said tissue. ".

Balas teaches a method of analyzing tissue samples by applying a chemical agent to the skin and monitoring optical signal reflecting off the tissue to develop images similar to that of Thirion. In addition, Bales further teaches applying a chemical agent to the tissue (paragraph 20 lines 1-5).

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Bales before him at the time the invention was made, to modify

the capturing images taught by Thirion to include the method of utilizing a chemical compound generating images by reflection over a period of time of Bales, in order to obtain a system that uses multiple method of generating a image and analyzing those images.

One would have been motivated to make such a combination because applying the chemical generates different types of images to aid in diagnosis of lesion tissues would have been obtained, as taught by Bales.

In regards to claim 10, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "said obtaining step comprises collecting an optical signal.".

Bales teaches a method of analyzing tissue samples by applying a chemical agent to the skin and monitoring optical signal reflecting off the tissue to develop images similar to that of Thirion. In addition, Bales further teaches said obtaining step comprises collecting an optical signal (paragraph 64) [The captured optical signal comprise the optical signal generated by the marker-tissue interaction and the light emitted from the endogenous components of the tissue. In many cases the recorded response of the components of the tissue constitute noise, since it occludes the generated optical signal, which caries the diagnostic information.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Balas before him at the time the invention was made, to modify the imaging system taught by Thirion to include the optical image system to capture fluorescence and reflecting lights of Balas, in order to obtain a system that the ability to digitalize tissue sample for correlation and which also incorporates optical signal imagery.

One would have been motivated to make such a combination because it allows the patient to have movement tissue without affecting the quality of the image, as taught by Bales. In addition, the system sampling tissue may be cervical, ear, oral, skin, esophagus, or stomach tissue (paragraph 20), as taught by Bales.

In regards to claim 11, Thirion in view of Bales discloses optical signal comprises fluorescence illumination (paragraph 64 line 7-10).

In regards to claim 12, Thirion in view of Bales discloses said optical signal comprises reflectance illumination (paragraph 64 line 7-10).

In regards to claim 23, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "processing said two or more images to compensate for a relative motion between said tissue and a detection device".

Balas teaches a system that allows some kinetic movement while generating the images of lesion tissues similar to that of Thirion. In addition, Balas further teaches

processing said two or more images to compensate for a relative motion between said tissue and a detection device (paragraph 65) [FIG. 2, illustrates a method for capturing in two spectral bands simultaneously and in any spatial point of the area under analysis, the kinetics of the alterations in the characteristics of the remitted from the tissue light, before and the after the administration of the contrast enhancing agent. The remitted from the tissue light, is collected and focused by the optical imaging module (L) and passes through a beam splitting (BSP) optical element. Thus, two identical images of the tissue (T) are generated,].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Balas before him at the time the invention was made, to modify the motion image generator taught by Thirion to include the motion kinetic of the area under analysis of Balas, in order to obtain a system that allow generating images while tissue having motion to produce clear images.

One would have been motivated to make such a combination because to improve the precision in the calculation of the curves in any spatial point that express the kinetics of marker-tissue interaction as taught by Balas.

In regards to claim 29, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite, "one of more optical signals based at least in part on said segmenting".

Balas teaches a system that allows some kinetic movement while generating the images of lesion tissues similar to that of Thirion. In addition, Balas further teaches processing one or more optical signals based at least in part on said segmenting (paragraph 64) [The captured optical signal comprise the optical signal generated by the marker-tissue interaction and the light emitted from the endogenous components of the tissue. In many cases the recorded response of the components of the tissue constitute noise, since it occludes the generated optical signal, which caries the diagnostic information.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Balas before him at the time the invention was made, to modify the imaging system taught by Thirion to include the optical image system to capture fluorescence and reflecting lights of Balas, in order to obtain a system that the ability to digitalize tissue sample for correlation and which also incorporates optical signal imagery.

One would have been motivated to make such a combination because it allows the patient to have movement tissue without affecting the quality of the image, as taught by Bales. In addition, the system sampling tissue may be cervical, ear, oral, skin, esophagus, or stomach tissue (paragraph 20), as taught by Bales.

In regards to claim 32, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "determining a characteristic of said tissue comprises classifying a region of tissue as one of the group consisting of normal squamous tissue, metaplasia, CIN I, and CIN II/CIN III. "

Balas teaches a system to generate image of lesion tissue similar to that of Thirion. In addition, Balas further teaches determining a characteristic of said tissue comprises classifying a region of tissue as one of the group consisting of normal squamous tissue, metaplasia, CIN I, and CIN II/CIN III (paragraph 21) [In another aspect, the present invention features a method for the in vivo diagnosis of a tissue abnormality, e.g., a tissue atypia, a tissue dysplasia, a tissue neoplasia (such as a cervical intraepithelial neoplasia, CINI, CINII, CINIII) or cancer, in a subject. The method includes contacting a tissue in a subject with a pathology-differentiating agent, e.g., an acetic acid solution or a combination of solutions selected from a plurality of acidic and basic solutions, exposing the tissue in the subject to optical radiation; and monitoring the intensity of light emitted from the tissue over time, thereby diagnosing a tissue abnormality in a subject.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Balas before him at the time the invention was made, to modify the classification of tissue taught by Thirion to include the different types of classification to tissue of Balas, in order to obtain a system that searches for lesion in tissue, and categorizes the tissue into groups to allow a through analyzes of the tissues.

One would have been motivated to make such a combination because it allows a doctor to view different types of tissue and become aware of they type of threat the lesion imposes on the patient, as taught by Bales. In addition, the system sampling tissue may be cervical, ear, oral, skin, esophagus, or stomach tissue (paragraph 20), as taught by Bales.

In regards to claim 39, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite " said first known characteristic is CIN II/CIN III and said second known characteristic is absence of CIN II/CIN III. ".

Balas teaches a system to generate image of lesion tissue similar to that of Thirion. In addition, Balas further teaches said first known characteristic is CIN II/CIN III and said second known characteristic is absence of CIN II/CIN III. (paragraph 21, Note the examiner interprets the tissue are analyzed for CIN II, or CIN III, for abnormality.) [In another aspect, the present invention features a method for the in vivo diagnosis of a tissue abnormality, e.g., a tissue

atypia, a tissue dysplasia, a tissue neoplasia (such as a cervical intraepithelial neoplasia, CINI, CINII, CINIII) or cancer, in a subject. The method includes contacting a tissue in a subject with a pathology-differentiating agent, e.g., an acetic acid solution or a combination of solutions selected from a plurality of acidic and basic solutions, exposing the tissue in the subject to optical radiation; and monitoring the intensity of light emitted from the tissue over time, thereby diagnosing a tissue abnormality in a subject.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Balas before him at the time the invention was made, to modify the classification of tissue taught by Thirion to include the different types of classification to tissue of Balas, in order to obtain a system that searches for lesion in tissue, and categorizes the tissue into groups to allow a through analyzes of the tissues.

One would have been motivated to make such a combination because it allows a doctor to view different types of tissue and become aware of they type of threat the lesion imposes on the patient, as taught by Bales. In addition, the system sampling tissue may be cervical, ear, oral, skin, esophagus, or stomach tissue (paragraph 20), as taught by Bales.

Claims 37,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Uppaluri (U.S. Patent number 6,466,687)

In regards to claim 35, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite "applying a classification rule based at least in part on said first plurality of reference sequences and said second plurality of reference sequences."

Uppaluri teaches system that analyzes lesion tissue a similar to that of Thirion. In addition, Uppaluri further teaches applying a classification rule based at least in part on said first plurality of reference sequences and said second plurality of reference sequences (Figure 1 item 145, col. 18 lines 20-45, Note that examiner interprets that the table is used demonstrated the different types of classification of tissue).

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Uppaluri before him at the time the invention was made, to modify the to add more classification categories other than just T, tissue, & L, lesion, taught by Thirion to include the more classification of tissue image samples of Uppaluri, in order to obtain a system that allows a user to classify normal tissue, lesion, and etc within the sample image.

One would have been motivated to make such a combination because the system allow diagnosis of tissue pathology using a diagnostic medical image, and, more

particularly, to a method and apparatus for detecting and diagnosing the presence of pulmonary tissue pathology from CT images using an automated texture analysis procedure would have been obtained, as taught by Uppaluri. In addition, another motivation to combine the reference is that the processing of two medical images obtain at different moments has been described, and the process may equally apply to images in another field, as taught by Thirion.

In regards to claim 37, Thirion states a system that compares images for lesion, with in the human tissue. The images are collected, segment to parts that are relevant, and then compared to view the difference.

The difference between the claims and Thirion is the claims recite, "the slope of a curve at a given point fitted to one of said plurality of mean signal intensity data series."

Uppaluri teaches system that analyzes lesion tissue a similar to that of Thirion. In addition, Uppaluri further teaches the slope of a curve at a given point fitted to one of said plurality of mean signal intensity data series (Figure 8 items 800-870, Note that the system takes the average of area of interest, determines the best slop, and then use re-generates the image, or constructs a new image.).

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Uppaluri before him at the time the invention was made, to modify the include the slope taught by Thirion to include the a system that uses a linear slope of Uppaluri, in order to obtain a system that utilizes slope for generating the images for the segmentation process.

One would have been motivated to make such a combination because the system allow diagnosis of tissue pathology using a diagnostic medical image, and, more particularly, to a method and apparatus for detecting and diagnosing the presence of pulmonary tissue pathology from CT images using an automated texture analysis procedure would have been obtained, as taught by Uppaluri. In addition, another motivation to combine the reference is that the processing of two medical images obtain at different moments has been described, and the process may equally apply to images in another field, as taught by Thirion.

Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thirion et al (WO98/53426, official translation U.S. Patent Number 6,373,998) in view of Uppaluri (U.S. Patent number 6,466,687), in further view of Utzinger (U.S. Patent Number 6,766,184).

In regards to claim 36, Thirion in view of Uppaluri disclose a system that analyzes tissue samples for lesion, and classifies each of tissue into groups for further examination.

The difference between the claims and Thirion in view of Uppaluri is the claims recite "performing a linear discriminant analysis to determine said classification rule. "

Utzinger teaches a system for generating images of tissue samples similar to that of Thirion in view of Uppaluri. In addition, Utzinger further teaches performing a linear discriminant analysis to determine said classification rule () [In each case, the algorithm development process, described in detail below,

consisted of the following major steps: (1) data pre-processing to reduce inter-patient variations, (2) data reduction to reduce the dimensionality of the data set, (3) feature selection and classification to develop algorithms which maximized diagnostic performance and minimized the likelihood of over-training in a training set, (4) evaluation of these algorithms using the technique of cross-validation.].

It would have been obvious to one of ordinary skill in the art, having the teachings of Thirion and Uppaluri and Utzinger before him at the time the invention was made, to modify the classification method taught by Thirion in view of Uppaluri to include the a linear function or algorithmic method of classification, in order to obtain a system the utilizes linear or algorithmic function for classifying tissue images.

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not discloses said chemical agent is selected from the group consisting of acetic acid, formic acid, propionic acid, butyric acid, Lugol's iodine, Shiller's iodine, methylene blue, toluidine blue, and indigo carmine as recited in claim 9.

The examiner interprets that the prior art has a method of diagnosis lesion tissue image, but does allow chemicals to be applied to the skin to generate the a digital image

of lesion tissue. The former prior art does not contain the Murkush group of the entire elements recited in claim 9.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to O'Neal R Mistry whose telephone number is (703) 305-4675. The examiner can normally be reached on 9am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M Mehta can be reached on (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

O'Neal Mistry
Assistant Patent Examiner
Art Unit 2625
o'neal.mistry@uspto.gov

ANDREW W. JOHNS
PRIMARY EXAMINER